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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,780	04/21/2004	Steven K. Striepeke	30610/40001	5236

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EXAMINER	
MOSS, KERI A	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
12/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,780	STRIEPEKE ET AL.	
	Examiner	Art Unit	
	KERI A. MOSS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/24/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24 and 58-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 and 58-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment filed September 24, 2008 is hereby acknowledged. Claims 24 and 58-60 are pending.

Response to Amendment

2. Previous rejection of claims 24 and 58-60 have been maintained but slightly modified in light of applicants' amendments and arguments.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims **24 and 58-60** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bostick et al. (USP 4,263,406) in view of Grundy et al. (USP 6,991,810).

Bostick discloses an apparatus comprising a sample entry port (Fig. 1, parts 37 and 38) a separator means being the ion exchange column (Fig. 1 part 1; column 3 lines 62-64) and a detection means (column 4 lines 2-6) including a detection reagent binding to the analyte (column 4 lines 58-69). Bostick specifically teaches that the invention is particularly useful for separating proteins from interfering species (column 1).

While Bostick et al. does not expressly teach measuring glycosaminoglycans with the disclosed detection means, Bostick gives examples of measuring the isoenzymes in body fluids. Thus, Bostick's invention is limited in application to isoenzymes and not other species in body fluids. At the time of invention, it was well known among those with ordinary skill in the art that glycosaminoglycans may be separated from interfering substances with ion exchange chromatography. Grundy et al. (USP 6,991,810) demonstrates this knowledge (column 11 lines 28-34). It was also well known at the time of invention that glycosaminoglycans may be detected using the detection reagent dimethylmethylene blue, which was known to bind to glycosaminoglycans. Grundy et al. also demonstrates this by citation to an article from 1986 (column 11 lines 36-40). In summary, Grundy demonstrates that it would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the device of Bostick by substituting the ion exchange chromatography separator means of Bostick with the ion exchange chromatography separator means of Grundy then further adding the detection reagent dimethylmethylene blue in order to obtain the predictable results of separating the glycosaminoglycans from interfering substances

and measuring the glycosaminoglycans. MPEP § 2141 (citing the KSR decision ruling that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR International Co. v. Teleflex Inc. (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007)).

Response to Arguments

6. Applicant's arguments Applicant's arguments filed September 24, 2008 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

7. Applicants argue that neither Bostick nor Grundy teaches separating glycosaminoglycans from interfering substances in a sample. Inherently, if a substance such as glycosaminoglycans is separated from any other substance, that other substance is an interfering substance as it was interfering in some way. If it weren't interfering, there would be no need to separate it out. Thus, a reference need not explicitly state that separation involves removing interfering substances since it is inherently implied that any separation removes an interfering substance. Furthermore, Bostick expressly teaches using its method to separate out interfering species (column 1). Thus, Bostick does in fact teach separating interfering substances from the analyte.

8. Applicants argue that the Examiner has not provided an adequate rationale for why one of ordinary skill in the art would look to the detection reagents of Grundy as

obvious variants of the detection reagents of Bostick. The rejection has been modified to explicitly address this concern. As stated in the rejection above, it would have been obvious for one of ordinary skill in the art to combine the known techniques of separating and measuring glycosaminoglycans with Bostick's device in order to obtain predictable results.

9. Applicant's argument that Grundy does not disclose separating glycosaminoglycans from the protein portion of the proteoglycan is beyond the scope of the instant claims.

10. Applicant argues that Bostick and Grundy fail to disclose "detection reagents that bind to separated glycosaminoglycans." While Grundy does not expressly state that its detection reagent binds to glycosaminoglycans, it was well known among those with ordinary skill in the art at the time of invention that dimethylmethylene blue binds to glycosaminoglycans (Grundy, column 11).

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Keri A. Moss/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797